JUL 6 - 2005

K051185

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
317-521-3723

Contact Person: Corina Harper

Date Prepared: May 6, 2005

Device Name

Proprietary name: Elecsys® CA 19-9 CalCheck™

Common name: CA 19-9 CalCheck

Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys® CA 19-9 CalCheck™ is substantially equivalent to the currently marketed Elecsys® C-Peptide CalCheck™ (K040157).

Device Description

The Elecsys® CA 19-9 CalCheck™ is a lyophilized product consisting of CA 19-9 in a buffered human serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.

Intended use

Elecsys® CA 19-9 CalCheck™ is intended for use in the verification of the calibration established by the Elecsys® CA 19-9 reagent on the Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.

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Comparison to predicate device

The Elecsys® CA 19-9 CalCheck™ is substantially equivalent to the currently marketed Elecsys® C-Peptide CalCheck™ (K040157). The below tables compare Elecsys® CA 19-9 CalCheck™ with the predicate device, Elecsys® C-Peptide CalCheck™ (K040157).

Similarities

Characteristic	Elecsys® CA 19-9 CalCheck™	Predicate device Elecsys® C-Peptide CalCheck™
Intended Use	Elecsys® CA 19-9 CalCheck™ is intended for use in the verification of the calibration established by the Elecsys® CA 19-9 reagent on the Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.	Elecsys® C-Peptide CalCheck is intended for use in the verification of the calibration established by the Elecsys® C-Peptide reagent on the Elecsys® immunoassay systems.
Levels	Three	same
Format	Lyophilized	same
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow standing closed for 15 minutes, then mixing gently.	same
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20 – 25 °C : 4 hrs	same

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Differences

Characteristic	Elecsys® CA 19-9 CalCheck™	Predicate device Elecsys® C-Peptide CalCheck™
Matrix	Human serum with added CA 19-9	Buffered horse serum with added C-Peptide

Performance Characteristics

The Elecsys® CA 19-9 CalCheck™ was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 6 - 2005

Roche Diagnostics Corp.
c/o Ms Corina Harper
9115 Hague Rd.
Indianapolis, IN 46250

Re: k051185
Trade/Device Name: Elecsys CA 19-9 CalCheck
Regulation Number: 21 CFR 866.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: May 6, 2005
Received: May 9, 2005

Dear Ms Harper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051185

Device Name: Elecsys® CA 19-9 CalCheck™

Indications For Use:

The Elecsys® CA 19-9 CalCheck™ is intended for use in the verification of the calibration established by the Elecsys® CA 19-9 reagent on the Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051185

Prescription Use ___XX____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)